

PRV

PATENT- OCH REGISTRERINGSVERKET

Patentavdelningen

**Intyg
Certificat**

Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.



(71) Sökande St Jude Medical AB, Järfälla SE
Applicant (s)

(21) Patentansökningsnummer 0202347-1
Patent application number

(86) Ingivningsdatum 2002-07-30
Date of filing

Stockholm, 2003-02-13

*För Patent- och registreringsverket
For the Patent- and Registration Office*

Kerstin Gerdén
Kerstin Gerdén

Avgift
Fee 170:-

**PATENT- OCH
REGISTRERINGSVERKET
SWEDEN**

Postadress/Address
Box 5055
S-102 42 STOCKHOLM

Telefon/Phone
+46 8 782 25 00
Vx 08-782 25 00

Telex
17978
PATOREG S

Telefax
+46 8 666 02 86
08-666 02 86

5 **A heart monitoring device, a system including such a device
and use of the system**

BACKGROUND OF THE INVENTION

1. Field of the invention

10

The present invention relates to an implantable heart monitoring device comprising a control circuit. The control circuit is adapted to be connected to one or more sensor members suited to be positioned in or at the heart of a living being. At least a first of said sensor members is adapted to be positioned in the coronary sinus region of the heart and arranged to sense at least one constituent of blood. The control circuit is adapted to receive signals from said first sensor member, which received signals are related to said blood constituent. The control circuit is also arranged to sense the activity of the heart, via signals from said one or more sensor members, such that events signifying a heart cycle are detectable by said control circuit.

25 The invention also relates to a heart monitoring system including such a heart monitoring device and to the use of such a system.

2. Description of the prior art

30 Several different devices for monitoring the performance of a heart are known. Often these devices are also able to deliver stimulation pulses to the heart. The devices are often able to sense the electrical activity in the heart. It is also known to sense other physiological parameters, such as pressure, oxygen level, pH, nitric oxide, carbon dioxide, etc.

35

US-A-5 213 098 describes a cardiac stimulator with an oxygen saturation sensor positioned in the coronary sinus of the heart. This de-

vice is also able to sense the blood pressure and the electrical activity of the heart. The stimulator may be used to control the atrial stimulation in order to improve the filling of the ventricles.

5 US-A-5 199 428 describes a device for detecting myocardial ischemia. A pH sensor or an oxygen saturation sensor may be positioned in the coronary sinus. The device can be used to stimulate for example the left and/or right carotid sinus nerves in order to decrease cardiac workload.

10

US-A-6 236 873 B1 describes an electrochemical sensor for measuring the oxygen content in blood.

15

US-A-4 202 339 describes a sensor for measuring the oxygen saturation level in blood.

US-A-4 453 537 describes a device for sensing, inter alia, the carbon dioxide content in the blood.

20 US-A-5 582 170 describes a fibre optic sensor for sensing the nitric oxide content in blood.

US-A-5 720 768 describes different possible electrode positions in order to stimulate or sense the different chambers of the heart.

25

US-A-6 070 100 describes that electrodes may be positioned in both the left and the right atrium as well as in or at the left and the right ventricles. The document describes the possibility of sensing the impedance between different electrodes. The sensed impedance values may be used to improve the cardiac output.

30

US 5,156,147 describes a pacemaker which has a hemodynamic sensor which is arranged to provide a signal representing the pumping performance of the heart. The hemodynamic sensor may be a piezo-electric pressure sensor.

35

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an implantable heart monitoring device, which in a relatively simple manner is able to monitor the heart condition. A further object is to provide such a device, which by means of a single sensor for a blood constituent is able to derive information about the heart condition. A still further object is to achieve an implantable heart monitoring system comprising such a device and to provide a use of such a system.

10

The above objects concerning the device are achieved by an implantable heart monitoring device of the kind defined in the first paragraph above and wherein the control circuit is also arranged to enable the following:

- 15 a) in response to signals from said first sensor member determine a first value related to said blood constituent during a first portion of a heart cycle, and
- b) in response to signals from said first sensor member determine a second value related to said blood constituent during a
- 20 second portion of a heart cycle.

With the heart monitoring device according to the invention, it is thus possible to obtain, from one and the same sensor member, different values for a blood constituent during different portions of a heart cycle. These values, and the relationship between these values, can provide important information about the condition of the heart. In particular, if the first sensor member is positioned in the coronary sinus of the heart, important information may be obtained. The blood in the coronary sinus is primarily the blood which comes from the cardiac venous system and exits into the right atrium. However, some blood may also enter from the right atrium into the coronary sinus. The blood in the right atrium normally represents the mixed venous blood of the body. By monitoring said blood constituent during different portions of a heart cycle, important information of the condition of the heart may be obtained, since these monitored blood constituent values may represent both cardiac venous blood and mixed venous blood. The advantages of the inven-

35

tion will become clear from the description below. The blood constituent that is sensed by the first sensor member will primarily be exemplified by the oxygen content in the blood, in particular by the partial pressure of oxygen in the blood. However, the invention is also applicable for sensing other blood constituents, such as the saturation level of oxygen, the carbon dioxide content, the content of nitric oxide, the pH-level of the blood or the temperature etc. Since the heart monitoring device is also arranged to sense the activity of the heart, the control circuit can be arranged such that the blood constituent is measured during different well defined portions of the heart cycle.

According to one preferred embodiment of the invention, the control circuit is arranged such that the first portion of the heart cycle is during the diastolic portion of the heart cycle and the second portion of the heart cycle is during the systolic portion of the heart cycle. In particular, the second portion of the heart cycle can be within the later 70% of the systolic portion of the heart cycle. It will become clear from the following description that by selecting said first and second portions of the heart cycle in this manner, important information about the difference of said blood constituent in for example cardiac venous blood and mixed venous blood can be obtained.

According to one embodiment of the invention, the blood constituent in question is oxygen as has been explained above. The oxygen concentration in the cardiac venous blood and in the mixed venous blood carries important information about the heart condition. This will be explained later in this description.

According to one advantageous embodiment of the invention, the control circuit is arranged to monitor said first and second values over a plurality of heart cycles. It is thereby possible to monitor how said first and second values change with time.

According to one embodiment of the invention, the control circuit is arranged to trigger the heart monitoring device to carry out at least

one measure if said first and second values and/or a relationship between said first and second values fulfil a predefined condition. The condition may for example be that the first value is lower than a first predefined level and the second value is higher than a second predefined level. The condition may also be that the first value has decreased more than a first predefined amount over a plurality of heart cycles while the second value has decreased less than a second predefined amount over the same heart cycles. The relationship between said first and second values and/or how said values change with time carry important information about the heart condition. The measure to be carried out may for example be to control the delivery of stimulation pulses to the heart. Another measure could be to deliver a drug in response to the monitored values. A still further measure could be to deliver a warning signal. These measures may thus be used to improve the heart condition or to warn a patient or a physician such that, for example, a suitable drug will be taken by the patient.

According to another embodiment of the invention, the device is also arranged to enable the sensing of the activity level of a living being into which the heart monitoring device is implanted, wherein the control circuit is arranged such that also the sensed activity level is taken into account when determining whether said measure should be carried out. The monitored values of said blood constituent may thereby be seen in relation to the activity level of the living being in question. This enables an improved basis for decisions concerning a possible measure to be carried out.

The invention also provides a heart monitoring system comprising a heart monitoring device according to any of the above embodiments and one or more leads connected to the heart monitoring device, wherein said one or more sensor members, including said first sensor member, are positioned on said leads. The invention thus provides a system which may be implanted into a living being.

According to a preferred embodiment of the system, the first sensor member and said control circuit are arranged to sense the amount

of oxygen in the blood. Preferably, the first sensor member is located on a first lead, which is suited to be introduced into the coronary sinus of the heart such that the first sensor member can be positioned in the coronary sinus. Hereby, the above-mentioned advantages by positioning a sensor in the coronary sinus are obtained.

According to a further embodiment of the system, said first lead comprises at least a second sensor or electrode member, wherein said second sensor or electrode member is located closer to the distal end of said first lead than said first sensor member, and wherein said first lead is designed such that said second sensor or electrode member is arranged such that it can be introduced via the coronary sinus into a cardiac vein. Advantageously, the control circuit is arranged to enable the delivery of stimulation pulses to said second sensor or electrode member. Such a sensor or electrode member may be positioned via the great cardiac vein into for example the posterior, lateral or anterior vein of the left ventricle and may be used to stimulate the left ventricle of the heart.

According to a further embodiment, the system comprises, in addition to said first lead, at least a second lead, wherein said second lead comprises at least a third sensor or electrode member suited to be positioned in the right ventricle of the heart. Preferably, the control circuit is arranged to deliver stimulation pulses to both said second sensor or electrode member and to said third sensor or electrode member, so as to enable the delivery of stimulating pulses to both the ventricles of the heart. The third sensor or electrode member may of course also be used to sense events in the heart. According to one embodiment, it is thus possible to stimulate both the ventricles of the heart. This is advantageous for example when treating patients suffering from congestive heart failure.

As has been stated above, the invention also concerns the use of a heart monitoring system as defined above. According to this use, the system is implanted into a living being, wherein said first sensor member is positioned in the coronary sinus region in the heart of

said living being and wherein at least the features a) and b) mentioned above are carried out. The above-mentioned advantages can thereby be obtained.

- 5 The first and second portions of the heart cycle may thus be chosen such that the first value is related to the blood constituent in blood from the cardiac venous system and such that the second value is related to said blood constituent in mixed venous blood. The system may for example be used to detect the state of ischemia in the heart. The system may, as has been explained above, for example be used to sense the blood constituent oxygen. The system may thereby be used to deliver a warning signal or to carry out a therapy if said first and second values and/or a relationship between said first and second values fulfil a predefined condition.

15

BRIEF DESCRIPTION OF THE DRAWINGS

- Fig 1 shows schematically a heart monitoring system with a heart monitoring device connected to leads with sensor or electrode members positioned in a heart.

20

Fig 2 A shows schematically the coronary blood flow.

Fig 2 B shows schematically the aortic blood flow.

25

Fig 2 C shows schematically the blood flow in the coronary sinus.

Fig 2 D shows schematically the partial pressure of oxygen in the coronary sinus at rest.

30

Fig 2 E shows schematically an electrocardiogram.

Fig 3 shows a flow chart of the use of a heart monitoring system according to an embodiment of the invention.

35

Fig 4 shows a flow chart of the use of a heart monitoring system according to another embodiment of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

5 An embodiment of the invention will now first be described with reference to Fig 1. Fig 1 shows schematically a heart monitoring device 10. The device 10 comprises a housing 12. The device 10 is arranged such that it may be implanted in a human or animal being. A control circuit 14 is arranged within the housing 12. The device 10 may include an activity sensor 18 in order to enable the sensing of
10 the activity level of a living being into which the heart monitoring device 10 is implanted. The device 10 comprises a connector portion 16 to which one or more leads 30, 40, 50 may be connected. In the shown embodiment, there are thus three leads 30, 40, 50. However, the number of leads may be more or less than three.

15 A first lead 30 comprises a first sensor member 33, which is adapted to be positioned in the coronary sinus region of the heart. The first sensor member 33 is arranged to sense at least one constituent of blood. The first lead 30 may also comprise a second sensor or electrode member 31, 32 located closer to the distal end of the first lead 30 than the first sensor member 33. The illustrated embodiment also shows a second lead 40 with at least a third sensor or electrode member 41, 42. Furthermore, a third lead 50 is shown with sensor or electrode members 51, 52. The sensor or
20 electrode members 31, 41, 51 are located at the tip portion of the respective lead 30, 40, 50. These members may therefore be called tip electrodes. The electrodes 32, 42, 52 are located a little further up along the respective lead 30, 40, 50 and may be called ring electrodes. These sensors or electrode members 31, 32, 41, 42, 51, 52 are thus arranged as bipolar electrodes. It is of course possible that instead unipolar electrodes are used. The electrode members
25 31, 32, 41, 42, 51, 52 may be used to sense the activity of the heart and/or to deliver stimulation pulses to the heart.

30 At least one sensor member, in the shown embodiment the sensor member 33, is designed to sense a blood constituent. The blood constituent may for example be the partial pressure of oxygen in the

blood. However, as has been mentioned above, the sensor member 33 may instead be designed to sense other blood constituents, such as the oxygen saturation level, carbon dioxide, nitric oxide, pH or temperature.

5

Fig 1 also schematically shows a heart with a right atrium RA, a right ventricle RV, a left atrium LA and a left ventricle LV. The first lead 30 with the first sensor member 33 is designed such that it can be introduced via the right atrium RA into the coronary sinus region of the heart. The first lead 30 may also be introduced further into the coronary venous system such that the second sensor or electrode member 31, 32 is introduced, for example, via the great cardiac vein into the posterior, lateral or anterior vein of the left ventricle. With such a position of the second sensor or electrode member 31, 32, it is for example possible to stimulate the left ventricle LV of the heart. The portion of the first lead 30 that is introduced into the cardiac venous system is here shown with a hatched line.

The second lead 40 is here shown to be introduced via the right atrium RA into the right ventricle RV such that the third sensor or electrode member 41, 42 is located close to the apex of the right ventricle RV. The third sensor or electrode member 41, 42 may be used to sense the electrical activity of the heart in the right ventricle RV and to deliver stimulation pulses to the right ventricle RV. A third lead 50 is here shown to be introduced into the right atrium RA and is thereby able to sense or deliver signals in this right atrium RA with the help of the sensor or electrode members 51, 52. The leads 30, 40, 50 suitably comprise electrical conductors, or other conductors, in order to conduct signals between the sensor or electrode members 31, 32, 33, 41, 42, 51, 52 and the control circuit 14, such as is well known to a person skilled in the art.

The device 10 may also be provided with means 60, which makes it possible to deliver a drug into the body in which the device 10 is implanted. The device 10 may also be provided with means 70 for generating a warning signal. The warning signal may for example be communicated via wireless communication to an external device

in the possession of the person into whom the device 10 is implanted or of a physician.

5 The control circuit 14 is thus adapted to receive signals from the first sensor member 33, which received signals are related to said blood constituent. The control circuit 14 is also arranged to sense the electrical activity of the heart, via signals from said one or more sensor members 31, 32, 33, 41, 42, 51, 52. Thereby, events signifying a heart cycle are detectable by the control circuit 14. The control circuit 14 is also arranged to enable the determination of a first value related to the blood constituent during a first portion of the heart cycle and to determine a second value related to the blood constituent during a second portion of the heart cycle. The different portions of the heart cycle may thus be detected by said one or more sensor members.

20 A heart monitoring system according to the invention comprises the heart monitoring device 10 together with one or more of the leads 30, 40, 50 and at least said first sensor member 33 positioned on the lead 30.

25 Fig 2 A-E show the variation of different parameters for corresponding parts of a heart cycle. The X-axis represents the time t and the Y-axis represents the different parameters. The systolic part of the heart cycle starts approximately at the hatched line 61 and ends at approximately the hatched line 62, where the diastolic portion of the heart cycle starts.

30 Fig 2 A shows schematically the blood flow in ml/min in the coronary artery.

Fig 2 B shows schematically the aortic blood flow in l/min.

35 Fig 2 C shows very schematically an example of the blood flow in the direction out from the coronary sinus in ml/min. It can be noted that during a portion of the heart cycle, primarily during the systolic portion, the blood flow is here negative. This means that blood dur-

ing this portion flows in from the right atrium RA into the coronary sinus. This happens normally during the ventricular contraction.

5 Fig 2 D shows very schematically an example of how the partial pressure of oxygen, in kPa, may vary in the coronary sinus during the heart cycle. During the systolic phase, in particular during the latter 70% or the latter half of the systolic portion of the heart cycle, the oxygen partial pressure represents the oxygen partial pressure in mixed venous blood, since, as explained above, the mixed venous blood from the right atrium RA tends to enter into the coronary sinus. Before the start of the systolic portion of the heart cycle, the partial pressure of oxygen in the coronary sinus represents the partial pressure of oxygen in the coronary venous blood.

15 Fig 2 E shows an electrocardiogram (ECG) during the heart cycle shown in the figures. P here represents the P-wave, R represents the QRS-complex and T represents the T-wave.

20 The concentration of different constituents of blood carries information about the heart condition. For example, the concentration of nitric oxide indicates the vasoconstriction-vasodilatation and may therefore, if measured in the cardiac venous blood, be used as an indication of biochemical events. The amount of lactic acid, and thereby the pH-value indicates whether anaerobic metabolism occurs. The different blood constituents may differ in cardiac venous blood as compared to in mixed venous blood. This fact is used according to the present invention in order to monitor the cardiac function and to detect if the heart does not function properly. In the description below, the partial pressure of oxygen will be used as an example of a blood constituent. It should be noted that the quantities mentioned are only given as examples. These quantities may vary between different living beings. The different quantities and the criteria for carrying out different measures should therefore be adapted to the particular living being using the invention.

35 When the living being is at rest, the partial pressure of oxygen in mixed venous blood may be about 5.3 kPa. The oxygen partial

pressure in coronary venous blood in the coronary sinus may be about 2.3 kPa. When the living being in question is at a higher activity level (exercise), the oxygen partial pressure in mixed venous blood can decrease to about 2.0 kPa. However, the oxygen partial pressure in the cardiac venous blood normally does not decrease substantially during exercise but remains at approximately 2.3 kPa. However, at hard exercise, the partial pressure of oxygen in the cardiac venous blood may be reduced to about 2.0 kPa. These insights may be used to control a heart monitoring device according to the present invention.

Figs 3 and 4 show flow charts of the use of a heart monitoring system according to different embodiments of the invention. At the same time, these figures show how the heart monitoring device according to the invention operates. Fig 3 thus shows that a sensor, i.e. the mentioned first sensor member 33, is positioned in the coronary sinus of a living being. How to insert a lead into the coronary sinus is well known to a person skilled in the art and will therefore not be explained more closely here. The control circuit 14 is arranged to determine a first value of the blood constituent during a first portion of the heart cycle. Furthermore, the control circuit 14 is arranged to determine a second value related to the blood constituent during a second portion of the heart cycle. Of course, the first portion of the heart cycle is always different from the second portion of the heart cycle. The control circuit 14 can be arranged such that said first value of the blood constituent, in this example the partial pressure of oxygen, is measured during the diastolic portion of the heart cycle. The control circuit 14 may for example be arranged such that this first value is measured substantially around the P-wave. The control circuit is also arranged such that the second value of the blood constituent is measured during the systolic portion of the heart cycle. Preferably, the second value is measured during the later 70% of the systolic portion of the heart cycle, for example substantially about the time of the occurrence of the T-wave. The first value is thus related to the oxygen partial pressure in coronary venous blood and the second value is related to the partial pressure of oxygen in primarily mixed venous blood.

Preferably, the control circuit 14 is arranged to monitor the first and second values over a plurality of heart cycles. In Fig 3, this is represented by the loop that is performed a number of times. This can
 5 be done in order to achieve a reliable value, for example by determining said first and second values as an average value over some heart cycles. It is also possible to monitor said first and second values over several heart cycles, or all the time, in order to monitor how these values change with time.

10 The control circuit 14 is arranged to trigger the heart monitoring device 10 to carry out at least one measure if the first and second values and/or a relationship between said first and second values fulfil a predefined condition. If the predefined condition is not fulfilled,
 15 then no particular measure is carried out, but the device 10 may directly or later be arranged to carry out a new determination of said first and second values. This is indicated by the hatched line starting at N. The predefined condition may be that the first value is lower than a first predefined level L1 and the second value is higher than a second predefined level L2. For example, in case the first value, i.e. the partial pressure of oxygen in the cardiac venous blood, is lower than for example 2.1 kPa while the second value, i.e. the partial pressure of oxygen in mixed venous blood, is higher than for example 3.0 kPa, then a measure can be carried out. The
 20 described situation means that the partial pressure of oxygen in mixed venous blood indicates that the living being in question is not under hard exercise although the partial pressure of oxygen in cardiac venous blood is quite low. This is an indication that the heart does not function properly, for example due to overload or due to an ischemic event. The measure to be carried out may for example be to control the delivery of stimulation pulses to the heart, for example by reducing the pacing rate, or to deliver a drug or to deliver a warning signal as has been described above.

35 Fig 4 shows another example of how the heart monitoring device according to the invention may operate. The first steps are here the same as in connection with Fig 3. The loop is performed a number

of times. In this case, however, the predefined condition is that the first value has decreased more than a first predefined amount A1 over a plurality of heart cycles while the second value has decreased less than the second predefined amount A2 over said plurality of heart cycles. For example, the first predefined amount may be that the partial pressure of oxygen in the cardiac venous blood has fallen more than 0.2 kPa (or a certain percentage of the original value), while the partial pressure of oxygen in mixed venous blood has decreased less than for example 1.0 kPa (or a certain percentage of the original value). This, again, is an indication of the fact that the heart is not working properly. Also in this case, the measure can be that the delivery of stimulation pulses to the heart is controlled, that a drug is released or that a warning signal is delivered. It should be noted that it is of course possible to combine the two manners of operating the device disclosed in Figs 3 and 4.

Figs 3 and 4 thus also show manners of using the heart monitoring system according to the invention. The system may thus be used in order to detect a state of overload or ischemia in the heart. As has been mentioned above, the system may be arranged such that stimulating pulses may be delivered to both the ventricles RV, LV of the heart. The device 10 and the system may of course be arranged such that the delivery of the stimulation pulses is changed in an iterative process based on the detected and monitored first and second values. In this manner, the delivery of the stimulation pulses may be adjusted until a more normally operating heart condition is detected. As mentioned above, the control circuit 14 may be arranged also to sense the activity level of the living being into which the device 10 is implanted. In this manner, a further indication of the activity level of the living being in question is obtained. The control circuit 14 may thereby be arranged to detect whether said first and second values, or the change of said first and second values, correspond to that which is considered normal when the living being in question is at rest or is at a high activity level.

Although the invention has primarily been described in connection with sensing the partial pressure of oxygen, the invention is also

applicable to other blood constituents like those mentioned above. For example, the half-time of nitric oxide is very short. This means that mixed venous blood will contain small amounts of nitric oxide while the level in the coronary venous blood is highly dependent on the intrinsic regulation of the cardiac perfusion. Therefore, similar conditions to those described above may be predefined for controlling the heart monitoring device also in response to the detection of first and second values concerning nitric oxide. Different predefined conditions may of course be set up for the different blood constituents.

Examples of different sensors that may be used are given in the documents cited above. For example, a sensor suitable for detecting the partial pressure of oxygen is given in the above cited US-A-6 236 873.

The invention is not limited to the described embodiments but may be varied and modified within the scope of the following claims.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

Claims

1. An implantable heart monitoring device (10) comprising:
a control circuit (14),
5 said control circuit (14) being adapted to be connected to one
or more sensor members (31, 32, 33, 41, 42, 51, 52) suited to be
positioned in or at the heart of a living being, at least a first (33) of
said sensor members being adapted to be positioned in the coro-
nary sinus region of the heart and arranged to sense at least one
10 constituent of blood, said control circuit (14) being adapted to re-
ceive signals from said first sensor member (33), which received
signals are related to said blood constituent, said control circuit (14)
also being arranged to sense the activity of the heart, via signals
from said one or more sensor members (31, 32, 33, 41, 42, 51, 52),
15 such that events signifying a heart cycle are detectable by said
control circuit,
 said control circuit (14) also being arranged to enable the fol-
lowing:
a) in response to signals from said first sensor member (33) de-
20 termine a first value related to said blood constituent during a
first portion of a heart cycle, and
b) in response to signals from said first sensor member (33) de-
termine a second value related to said blood constituent dur-
ing a second portion of a heart cycle.
25
2. An implantable heart monitoring device (10) according to
claim 1, wherein said control circuit (14) is arranged such that said
first portion of a heart cycle is during the diastolic portion of the
heart cycle and said second portion of a heart cycle is during the
30 systolic portion of a heart cycle.
3. An implantable heart monitoring device (10) according to
claim 2, wherein said control circuit (14) is arranged such that said
second portion of a heart cycle is within the later 70% of the systolic
35 portion of a heart cycle.

4. An implantable heart monitoring device (10) according to any of the preceding claims, wherein said blood constituent is oxygen.
5. An implantable heart monitoring device (10) according to any of the preceding claims, wherein said control circuit (14) is arranged to monitor said first and second values over a plurality of heart cycles.
- 10 6. An implantable heart monitoring device (10) according to any of the preceding claims, wherein said control circuit (14) is arranged to trigger the heart monitoring device (10) to carry out at least one measure if said first and second values and/or a relationship between said first and second values fulfil a predefined condition.
- 15 7. An implantable heart monitoring device (10) according to claim 6, wherein said predefined condition is that said first value is lower than a first predefined level and said second value is higher than a second predefined level.
- 20 8. An implantable heart monitoring device (10) according to claim 5 in combination with claim 6 or 7, wherein said predefined condition is that said first value has decreased more than a first predefined amount over a plurality of heart cycles while said second value has decreased less than a second predefined amount over
25 said plurality of heart cycles.
9. An implantable heart monitoring device (10) according to any of the claims 6-8, wherein the heart monitoring device (10) is arranged to also enable the delivery of stimulation pulses to the heart
30 and wherein said measure is to control the delivery of said stimulation pulses to the heart.
10. An implantable heart monitoring device (10) according to any of the claims 6-9, wherein the heart monitoring device (10) is arranged to enable the delivery of a drug to the living being into which
35 the heart monitoring device is implanted and wherein said measure is to control the delivery of said drug.

REV 0001 X

11. An implantable heart monitoring device (10) according to any of the claims 6-10, wherein the heart monitoring device (10) is arranged to enable the delivery of a warning signal and wherein said measure is to deliver said warning signal.

12. An implantable heart monitoring device (10) according to any of the claims 6-11, wherein said heart monitoring device (10) is arranged to enable the sensing of the activity level of a living being into which the heart monitoring device (10) is implanted, wherein said control circuit (14) is arranged such that also the sensed activity level is taken into account when determining whether said measure should be carried out.

13. An implantable heart monitoring system comprising:
a heart monitoring device (10) according to any of the preceding claims,
one or more leads (30, 40, 50) connected to said heart monitoring device (10), wherein said one or more sensor members (31, 32, 33, 41, 42, 51, 52) including said first sensor member (33), are positioned on said leads (30, 40, 50).

14. An implantable heart monitoring system according to claim 13, wherein said first sensor member (33) and said control circuit (14) are arranged to sense the amount of oxygen in the blood.

15. An implantable heart monitoring system according to claim 13 or 14, wherein at least a first (30) of said leads is suited to be introduced into the coronary sinus of said heart and wherein said first sensor member (33) is positioned on said first lead (30) such that it can be positioned in the coronary sinus.

16. An implantable heart monitoring system according to claim 15, wherein said first lead (30) comprises at least a second sensor or electrode member (31, 32), wherein said second sensor or electrode member (31, 32) is located closer to the distal end of said first lead (30) than said first sensor member (33), and wherein said first

lead (30) is designed such that said second sensor or electrode member (31, 32) is arranged such that it can be introduced via the coronary sinus into a cardiac vein.

- 5 17. An implantable heart monitoring system according to claim 16, wherein said control circuit (14) is arranged to enable the delivery of stimulation pulses to said second sensor or electrode member (31, 32).
- 10 18. An implantable heart monitoring system according to any of the claims 15-17, comprising, in addition to said first lead (30), at least a second lead (40), wherein said second lead (40) comprises at least a third sensor or electrode member (41, 42) suited to be positioned in the right ventricle (RV) of said heart.
- 15 19. Use of a heart monitoring system according to any of the claims 13-18, wherein said system is implanted into a living being, wherein said first sensor member (33) is positioned in the coronary sinus region in the heart of said living being and wherein at least
- 20 the features a) and b) of claim 1 are carried out.
20. Use according to claim 19, wherein said first and second portions of a heart cycle are chosen such that the first value is related to said blood constituent in blood from the cardiac venous system
- 25 and such that said second value is related to said blood constituent in mixed venous blood.
21. Use according to claim 19 or 20, wherein the system is used to detect a state of ischemia in said heart.
- 30 22. Use according to any of the claims 19-21, wherein said first sensor member (33) and the control circuit (14) are used to sense the blood constituent oxygen.
- 35 23. Use according to any of the claims 19-22, wherein said system is used to deliver a warning signal or to carry out a therapy if

said first and second values and/or a relationship between said first and second values fulfil a predefined condition.

CONFIDENTIAL

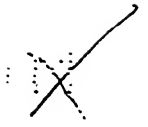
Abstract

The invention concerns an implantable heart monitoring device (10) comprising a control circuit (14) adapted to be connected to one or more sensor members (31, 32, 33, 41, 42, 51, 52). A first sensor member (33) is adapted to be positioned in the coronary sinus region of the heart and arranged to sense at least one constituent of blood. The control circuit (14) is arranged to sense the activity of the heart and also to enable the following:

- 5 a) in response to signals from said first sensor member (33) determine a first value related to said blood constituent during a first portion of a heart cycle, and
- b) in response to signals from said first sensor member (33) determine a second value related to said blood constituent during a
- 10 second portion of a heart cycle.

The invention also concerns a system including such a heart monitoring device and the use of such a system.

(Fig 1)



1/4

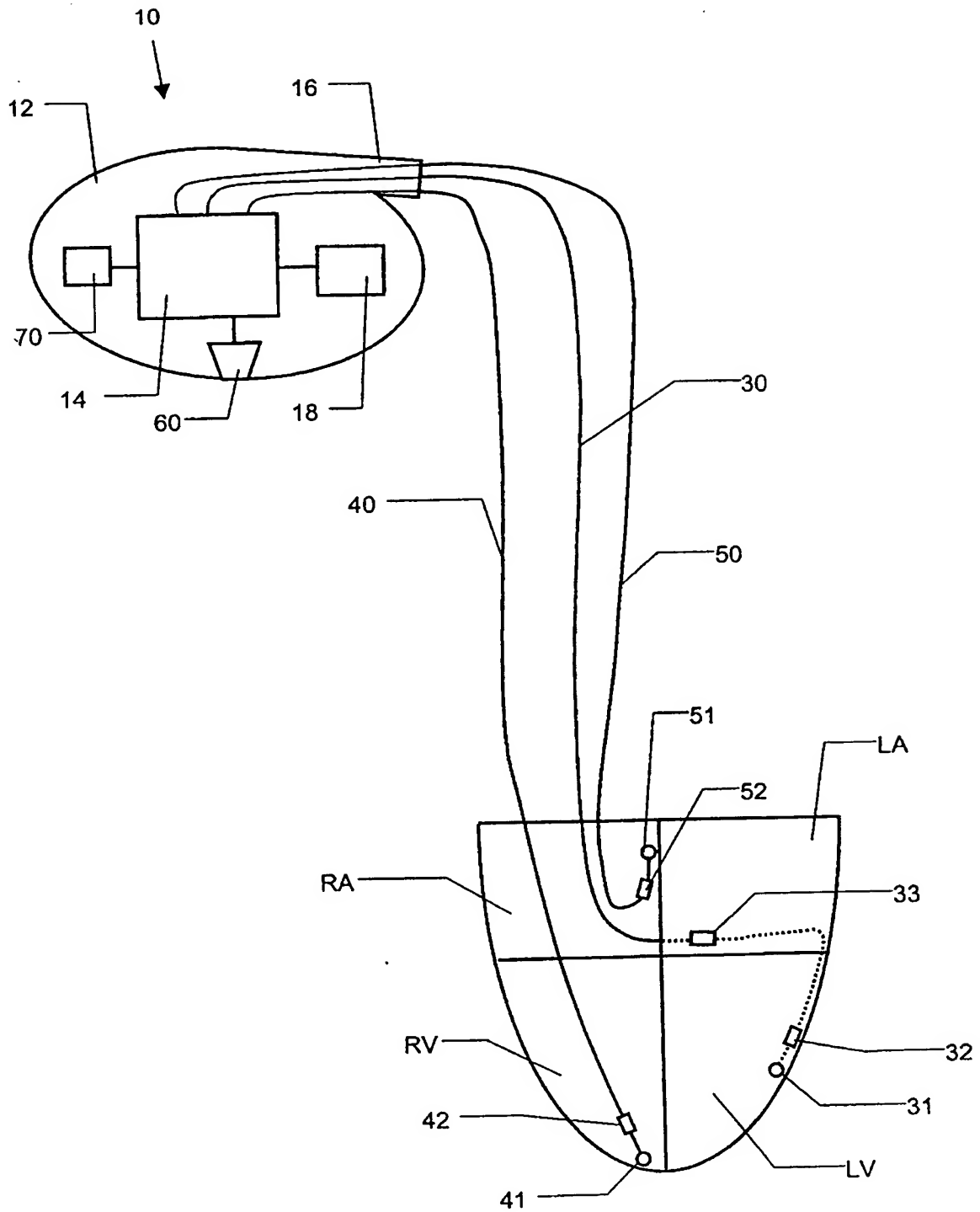


FIG 1

FIG 2 A

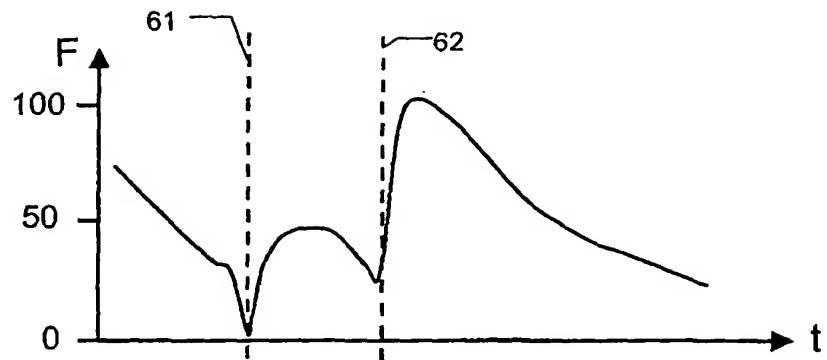


FIG 2 B

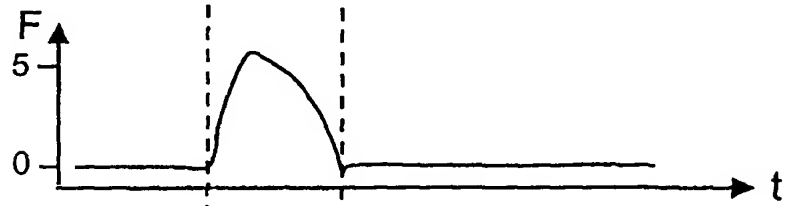


FIG 2 C

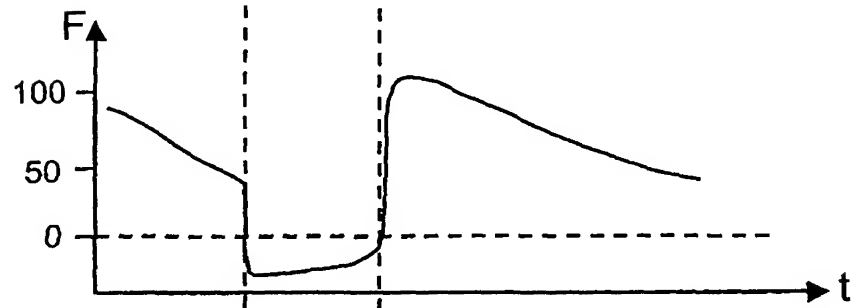


FIG 2 D

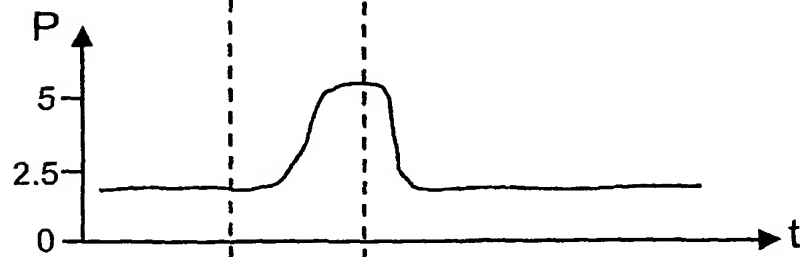
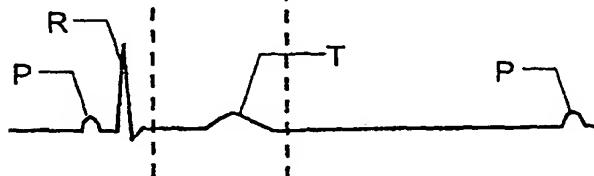


FIG 2 E



3/4

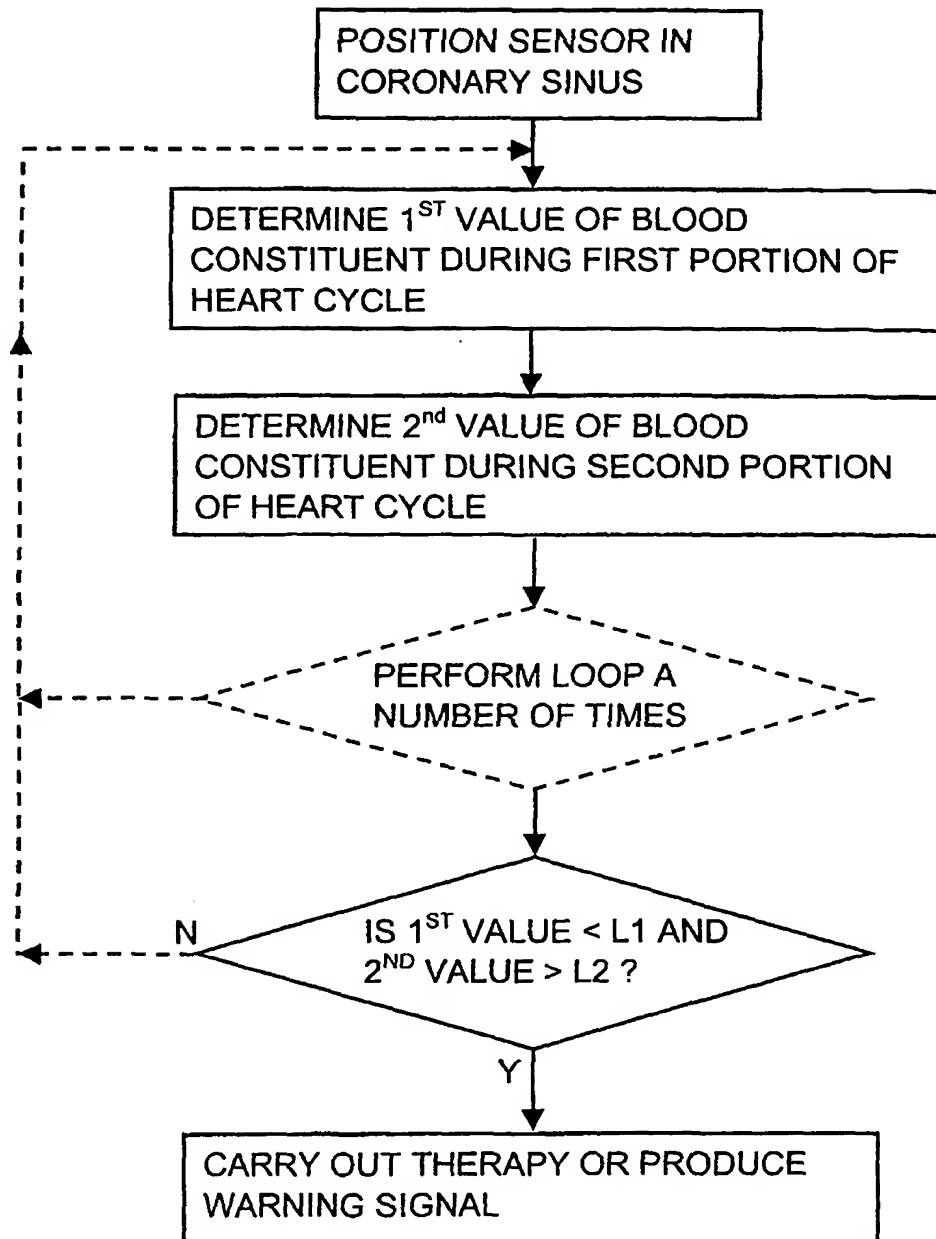


FIG 3

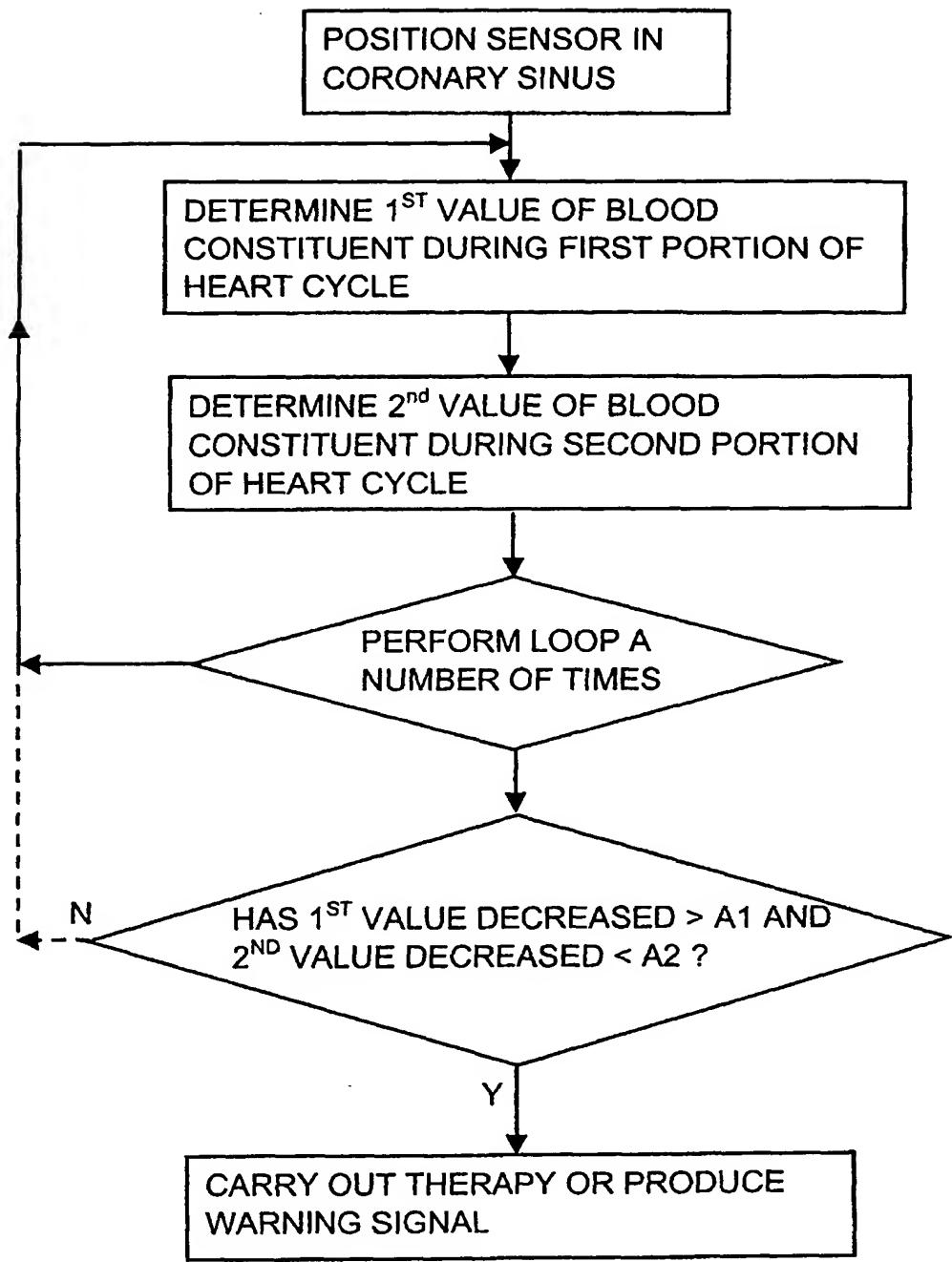


FIG 4